

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ORLANDO REGIONAL HEALTHCARE SYSTEM, INC.**

I. PREAMBLE

Orlando Regional Healthcare System, Inc. ("ORHS") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance by its officers, directors, and employees, specifically including employees within the Patient Financial Services Department of ORHS ("PFS employees"), with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs"). ORHS's compliance with the terms and conditions in this CIA shall constitute an element of ORHS's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, ORHS is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this CIA, ORHS voluntarily established a compliance program (known as the "Orlando Regional Healthcare System's Corporate Compliance Program" or "CCP") that applies to all ORHS facilities and entities. The CCP establishes corporate integrity policies and procedures and is aimed at ensuring that ORHS's participation in the Federal health care programs is in conformity with the statutes, regulations and other directives applicable to the programs. Pursuant to this CIA, ORHS agrees to continue the full operation of its CCP in accordance with the provisions set forth below for the term of this CIA. At a minimum, the CCP shall always contain as essential components the corporate integrity obligations enumerated below.

II. TERM OF THE CIA

The period of the compliance obligations assumed by ORHS under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory executes this CIA (the "effective date").

III. CORPORATE INTEGRITY OBLIGATIONS

ORHS shall maintain a compliance program that includes the following elements.

A. Compliance Officer and Committee.

Prior to the execution of this CIA, ORHS appointed a Director of Compliance and delegated to him the responsibility for coordinating the development and implementation of policies, procedures, and practices designed to ensure compliance with the requirements of the Federal health care programs. The Director of Compliance shall continue to make regular reports regarding compliance matters directly to the CEO and/or to the Board of Directors of ORHS and shall be authorized to report to the Board of Directors at any time. The Director of Compliance shall continue to be responsible for monitoring the day-to-day activities engaged in by ORHS to further its compliance objectives. In addition, the Director of Compliance shall be responsible for fulfilling the reporting obligations created under this CIA. In the event a new Director of Compliance is appointed during the term of this CIA, ORHS shall notify the OIG, in writing, within fifteen (15) days of such a change.

Prior to the execution of this CIA, ORHS also appointed a Compliance Committee and hired a departmental staff to support the Director of Compliance. During the term of this CIA, ORHS shall continue to maintain, at a minimum, a Compliance Committee that shall support the Director of Compliance in fulfilling his/her responsibilities.

B. Written Standards.

1. Code of Conduct. Prior to the execution of this CIA, ORHS established a written Code of Conduct that has been distributed to most ORHS employees. In addition ORHS has trained most of its employees on the Code of Conduct. ORHS will complete its distribution of and training on the Code of Conduct for all employees within ninety (90) days of the effective date of this CIA. As ORHS employees completed or will complete their Code of Conduct training, they have certified or will certify in writing, that they have received, read, understand, and will abide by the Code of Conduct. ORHS shall make promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees.

New ORHS employees shall receive the Code of Conduct training and shall complete the required certification within two (2) weeks after the commencement of their employment or within ninety (90) days of the effective date of the CIA, whichever is later.

ORHS will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed to ORHS employees within sixty (60) days of initiating such a change. ORHS employees shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. Policies and Procedures. Within ninety (90) days of the effective date of this CIA, ORHS shall develop and initiate implementation of written Policies and

Procedures about the operation of ORHS's compliance program and compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs.

The Policies and Procedures shall specifically address the submission of accurate and proper bills and claims, among other issues. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues through a confidential disclosure program as required by section III.E. ORHS shall assess and update as necessary the Policies and Procedures as appropriate and at least annually. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report required by section V.A. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be made available to all PFS employees. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. Training and Education.

1. **General Training.** Prior to the execution of this CIA, ORHS established a comprehensive training program for all its employees. That training program includes a general orientation that specifically addresses the CCP and the Code of Conduct. All PFS employees have received this general orientation, or will receive it

within ninety (90) days of the effective date of this CIA. Training materials relating to this general orientation shall be made available to the OIG upon request.

New PFS employees shall receive the general training described above within thirty (30) days of the beginning of their employment or contract or within ninety (90) days after the effective date of this CIA, whichever is later.

2. Specific Training. Prior to the execution of this CIA, ORHS also established a comprehensive specific training program for its PFS employees. All PFS employees have received in excess of fifty (50) hours of specific training in addition to the general orientation specified above. This training included a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program patients;
- b. policies, procedures and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement rules and statutes;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

The training materials from this specific training shall be made available to OIG upon request. The persons who provided the training are knowledgeable about the subject areas of billing and submission of claims to Federal health care programs.

Under its current training program, new PFS employees receive this specific training within sixty (60) days of the beginning of their employment or contract. No PHS employee has any responsibility for the preparation or submission of claims and/or the assignment of procedure codes prior to completing the first forty-eight (48) hours of this specific training in addition to other training. Every PFS employee participates in a recertification training program on an annual basis that provides additional specific training on reimbursement and billing issues, among other issues.

ORHS shall maintain the above-referenced training program for its PFS employees during the term of this CIA. In the alternative, if ORHS institutes another training program for the PFS employees, that program shall provide at least eight (8) hours of specific training covering, at a minimum, the items listed above in sections III.C.2(a-f).

3. Certification. Each ORHS PFS employee has certified, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Director of Patient Financial Services Training shall retain the certifications, along with specific course materials. These materials shall be made available to OIG upon request.

D. Review Procedures.

Prior to the execution of this CIA, ORHS established and implemented internal procedures, as outlined below, for reviewing its coding and billing functions. During each year of this CIA, ORHS shall continue to utilize the internal review procedures specified below or it shall implement comparable procedures. In the event that ORHS changes these internal review procedures, it shall inform the OIG, in writing, of such change within thirty (30) days of the implementation of the new procedure.

ORHS utilizes two significant internal procedures to review bills and claims for reimbursement that are submitted to third party payors. The first of these reviews relates to the "coding" of a patient's medical records and the second occurs immediately prior to the submission of a bill or claim to a payor. With regard to the first review, ORHS's coding staff reviews each patient's medical records and converts the information in the records to the appropriate billing codes to enable a bill or claim to be submitted to the payor. ORHS audits a sample of each of its coder's charts on a quarterly basis and requires that each coder's quality scores must exceed ninety-five percent (95%) accuracy.

As a second significant method of internal review, ORHS utilizes a computer software package that reviews each of ORHS's bills or claims which are submitted electronically prior to the time they are submitted to third party payors. All claims submitted to government payors are submitted electronically. The computer program utilizes a substantial number of custom and standard edits designed to insure the accuracy

of each bill or claim. If the bill or claim fails to satisfy each of the edits, it is not submitted to the payor. Instead, ORHS conducts a manual follow-up review of the bill or claim to insure that only proper bills and claims are submitted for payment.

ORHS shall include a summary of the results of its internal coding audits in its Annual Reports to the OIG. The audit section of each Annual Report shall: 1) explain the methodology used to make each determination required by the audit; 2) explain the audit results; and 3) identify any overpayments.¹ The listing of overpayments should include the amount of money, the program (e.g., Medicare, Medicaid (identified by State)), and name of the contractor to which the refund was made.

If any of these quarterly coding audits reveals that there have been any billing, claims submission, coding or other policies, procedures and/or practices that resulted in an overpayment and/or material deficiency,² ORHS shall notify the payor (e.g., the Medicare fiscal intermediary or carrier or the state Medicaid program) within thirty (30) days of discovering the material deficiency or overpayment. If ORHS learns of any overpayment, it shall promptly (but in no event later than sixty (60) days after discovering

¹ For purposes of this CIA, an "overpayment" shall mean the amount of money ORHS has received in excess of the amount due and payable under the Medicare, Medicaid, or other Federal health care program's statutes and regulations.

² For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Medicare and/or Medicaid programs; (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statutes, regulations or directives issued by the Health Care Financing Administration and/or its agents; or (iii) serious quality of care implications for federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

the overpayment) notify the payor and make appropriate refunds.³ Further, ORHS shall take remedial steps within sixty (60) days (or such additional time as may be reasonably necessary) to correct the problem, including preventing said overpayment or material deficiency from reoccurring.

If ORHS has identified a material deficiency, contemporaneous with its notification to the payor as provided above, ORHS shall notify OIG of: (1) the material deficiency (including any overpayment amounts); (2) ORHS' findings concerning the material deficiency; (3) ORHS' action(s) to correct and prevent such material deficiency from reoccurring; (4) the payor's name, address, and contact person where any overpayment was sent; (5) the date of the check and check number (or electronic transaction number) on which any overpayment was repaid.

ORHS shall annually engage the services of an independent review organization, such as an accounting firm or a consulting firm, to verify the accuracy of the methodologies employed by ORHS to conduct the quarterly coding audits explained above. For example, the independent review organization shall assess the method in which the audit samples are selected, whether the sample size is statistically valid, and whether the audit complies with generally accepted audit standards. ORHS shall request

³ In order to process the refund, the payor requires certain information. Therefore, the notice to the payor should: (1) state that the refund is being made pursuant to the terms of this CIA; and should describe and identify (2) the complete circumstances surrounding the overpayment; (3) the methodology by which the overpayment was determined; (4) the amount of the overpayment; (5) any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date); and (6) the provider identification number under which the repayment is being made.

the independent review organization to produce a report on its findings, which report shall be included in the Annual Report. The independent review organization must have expertise in billing, claims submission, coding, reporting and other requirements of the Medicare, Medicaid, and other Federal health care programs from which ORHS seeks reimbursement.

In the event that the OIG determines that it is necessary to conduct an independent audit or review to determine whether or the extent to which ORHS is complying with its obligations under this CIA, ORHS agrees to pay for the reasonable cost of any such audit or review by the OIG or any of its designated agents.

E. Confidential Disclosure Program.

Prior to the execution of this CIA, ORHS established a telephone "Compliance Line" that enables its employees, contractors, agents and other individuals to anonymously disclose any issues or questions associated with ORHS's policies, practices or procedures with respect to any Federal health care program believed by the individual to be inappropriate. During the term of this CIA, ORHS shall maintain this telephone hotline, or some other form of a confidential disclosure program that emphasizes a non-retribution, non-retaliation policy and includes a reporting mechanism for anonymous, confidential communication, to the Director of Compliance or some other individual not in the disclosing individual's chain of command. ORHS will continue to ensure that good faith internal investigations and proper follow-up are conducted of disclosures made

through its Compliance Line or any other disclosure program that may be implemented.

The Director of Compliance shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

1. ***Definition.*** For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. ***Screening Requirements.*** ORHS shall not hire, engage as a contractor or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, ORHS shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.arnet.gov/epl>) and the HHS/OIG Cumulative Sanction Report (available through the Internet at

<http://www.dhhs.gov/progorg/oig>) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within ninety (90) days of the effective date of this CIA, ORHS will review its list of current PFS employees against the Exclusion Lists. Within one hundred and fifty (150) days of the effective date of this CIA, ORHS will review its list of all remaining employees, contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, ORHS will review the lists once semi-annually. If ORHS has notice that an employee, agent, or physician has become an Ineligible Person, ORHS will remove such person from responsibility for, or involvement with, ORHS's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If ORHS has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with ORHS, within ten (10) days of receiving such notice ORHS will remove such individual from responsibility for, or involvement with, ORHS's business operations

related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

G. Notification of Proceedings.

Within thirty (30) days of discovery, ORHS shall notify OIG, in writing, of any ongoing government investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that ORHS or any of its employees, contractors/agents or physicians with staff privileges has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. ORHS shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Credible evidence of misconduct.* If ORHS discovers credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law concerning ORHS's practices relating to the Federal health care programs, then ORHS shall promptly report the probable violation of law to OIG. ORHS shall make this disclosure as soon as

practicable, but not later than thirty (30) days after becoming aware of the existence of the probable violation. The ORHS's report to OIG shall include:

- a. the findings concerning the probable violation, including the nature and extent of the probable violation;
- b. ORHS's actions to correct such probable violation; and
- c. any further steps it plans to take to address such probable violation and prevent it from recurring.

To the extent the misconduct involves an overpayment or material deficiency, the report shall include the information listed in section III.D regarding overpayments and material deficiencies.

2. *Inappropriate Billing.* If ORHS discovers inappropriate or incorrect billing through means other than internal coding audit referenced above in section III.D, ORHS shall follow the procedures in that section regarding overpayments and material deficiencies.

IV. NEW LOCATIONS

In the event that ORHS purchases or establishes new business units after the effective date of this CIA, ORHS shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider

number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and twenty (120) days after the effective date of this CIA, ORHS shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Director of Compliance required by section III.A;
2. the names and positions of the members of the Compliance Committee required by section III.A;
3. the summary of the Policies and Procedures required by section III.B.2;
4. a certification by the Director of Compliance that:
 - a. all PFS employees have completed the Code of Conduct certification required by section III.B.1;
 - b. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been made available to all pertinent ORHS PFS employees; and
 - c. all ORHS PFS employees have completed the training and executed the certification required by section III.C;

5. the identity of the independent review organization and the proposed start and completion dates of that organization's review of ORHS's internal coding audits; and
6. a summary of personnel actions taken pursuant to section III.F.

B. Annual Reports. ORHS shall submit to OIG an Annual Report with respect to the status and findings of ORHS's compliance activities.

The Annual Reports shall include:

1. any change in the identity or position description of the Director of Compliance and/or members of the Compliance Committee described in section III.A;
2. a certification by the Director of Compliance that:
 - a. all ORHS PFS employees have completed the annual Code of Conduct certification required by section III.B.1; and
 - b. all ORHS PFS employees have completed the training and executed the certification required by section III.C;
3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);
4. a summary of the results of ORHS's internal coding audits as well as a complete copy of the report prepared by the independent review

organization regarding the methodologies employed by ORHS for those audits;

5. ORHS's response/corrective action plan to any issues raised by its internal audits or the report of the independent review organization;

6. a summary of material deficiencies discovered and reported throughout the course of the previous twelve (12) months pursuant to III.D and III.H;

7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken

down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

8. a copy of the confidential disclosure log required by section III.E;

9. a description of any personnel action (other than hiring) taken by ORHS as a result of the obligations in section III.F;

10. a summary describing any ongoing government investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that ORHS or any of its employees, contractors/agents or physicians with staff privileges has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G.

The statement shall include a description of the allegation, the identity of

the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

11. a corrective action plan to address the probable violations of law identified in section III.H; and

12. a listing of all of the ORHS's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and thirty (30) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Director of Compliance under penalty of perjury, that: (1) ORHS is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Director of Compliance has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all

notifications and reports required under this CIA shall be submitted to the entities listed

below:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone: 202.619.2078
Fax: 202.205.0604

ORHS:

J. Stuart Showalter, JD, MFS
Director of Compliance
Orlando Regional Healthcare System, Inc.
1414 Kulh Avenue
Orlando, FL 32806-2093
Phone: 407.841.5111; extension 48897
Fax: 407.246.7083

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s), may examine ORHS's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) ORHS's compliance with the terms of this CIA; and (b) ORHS's compliance with the

requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by ORHS to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of ORHS's employees or ORHS billing employees/agents who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee or ORHS billing employee/agent and the OIG. ORHS agrees to assist OIG in contacting and arranging interviews with such employees and ORHS billing employees/agents upon OIG's request. ORHS's employees may elect to be interviewed with or without a representative of ORHS present.

VIII. DOCUMENT AND RECORD RETENTION

ORHS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA for six (6) years after the execution of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify ORHS prior to any release by OIG of information submitted by ORHS pursuant to its obligations under this CIA and identified upon submission by ORHS as trade secrets, commercial or financial

information and privileged and confidential under the FOIA rules. ORHS shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

ORHS is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, ORHS and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning ninety (90) days after the effective date of this CIA and concluding at the end of the term of this CIA, ORHS fails to maintain or institute any of the following:

- a. a Director of Compliance;
- b. a Compliance Committee;
- c. written Code of Conduct;
- d. written Policies and Procedures;

e. a training program; and

f. a confidential disclosure program.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day ORHS fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day ORHS:

a. hires or enters into a contract with or grants staff privileges to an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which ORHS can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);

b. employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, ORHS's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time

period during which ORHS can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person); or

c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, ORHS's business operations related to the Federal health care program (this Stipulated Penalty shall not be demanded for any time period before ten (10) days after ORHS received notice of the relevant matter or after the resolution of the matter).

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the ORHS fails to grant access) for each day ORHS fails to grant access to the information or documentation as required in section VII of this CIA.

5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to ORHS of the failure to comply) for each day ORHS fails to comply fully and adequately with any obligation of this CIA. In its notice to ORHS, the OIG shall state the specific grounds for its determination that the ORHS has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that ORHS has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify ORHS by personal service or certified mail of (a) ORHS's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, ORHS shall either (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event ORHS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until ORHS cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for the imposition of a Material Breach Penalty under section X.C.

2. *Timely Written Requests for Extensions.* ORHS may submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated

Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after ORHS fails to meet the revised deadline as agreed to by the
OIG-approved extension. Notwithstanding any other provision in this section, if
OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or
file the notification or report shall not begin to accrue until two (2) business days after
ORHS receives OIG's written denial of such request. A "timely written request" is
defined as a request in writing received by OIG at least five (5) business days prior to the
date by which any act is due to be performed or any notification or report is due to be
filed.

3. Form of Payment. Payment of the Stipulated Penalties shall be made by
certified or cashier's check, payable to "Secretary of the Department of Health and
Human Services," and submitted to OIG at the address set forth in section VI.

4. Independence from Material Breach Determination. Except as
otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or
otherwise set a standard for the OIG's determination that ORHS has materially breached

this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Monetary Penalty for Material Breach of This CIA.

1. *Material Breach Defined.* A material breach of this CIA means: (i) a failure by ORHS to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D; (ii) repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A; or (iii) a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above.

2. Notice of Material Breach and Intent to Collect Material Breach Penalty.

The parties agree that a material breach of this CIA by ORHS constitutes grounds for the OIG to impose an enhanced stipulated penalty that is separate and apart from the Stipulated Penalties described in section X.A-B. This monetary penalty (hereinafter referred to as the "Material Breach Penalty") shall be \$10,000 per day. Upon a determination by the OIG that ORHS has materially breached this CIA and that a Material Breach Penalty should be imposed, the OIG shall notify ORHS by certified mail of: (i) ORHS' material breach; and (ii) the OIG's intent to exercise its contractual right to impose the Material Breach Penalty (this notification is hereinafter referred to as the "Notice of Material Breach Letter"). In its Notice of Material Breach Letter, the OIG

shall state the specific grounds for its determination that ORHS has materially breached this CIA.

3. Opportunity to Cure. ORHS shall have thirty-five (35) days from the date of the Notice of Material Breach Letter to demonstrate to the OIG's satisfaction that:

- (a) ORHS is in full compliance with this CIA;
- (b) the alleged material breach has been cured; or
- (c) the alleged material breach cannot be cured within the thirty-five (35) day period, but that (i) ORHS has begun to take action to cure the material breach; (ii) ORHS is pursuing such action with due diligence; and (iii) ORHS has provided to the OIG a reasonable timetable for curing the material breach.

4. Penalty Letter. If, at the conclusion of the thirty-five (35) day period, ORHS fails to satisfy the requirements of section X.C.3, the OIG may impose the Material Breach Penalty on ORHS and the penalty will begin to accrue on that day. The OIG will notify ORHS in writing of its determination to impose the Material Breach Penalty (this letter shall be referred to hereinafter as the "Material Breach Penalty Letter"). Within fifteen (15) days of the date of the Material Breach Penalty Letter, ORHS shall either: (i) cure the material breach to the OIG's satisfaction and pay the applicable Material Breach Penalty; or (ii) request a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of material breach, pursuant to the agreed upon provisions set

forth below in section X.D. In the event ORHS elects to request an ALJ hearing, the Material Breach Penalties shall continue to accrue until ORHS cures, to the OIG's satisfaction, the alleged material breach in dispute.

D. Dispute Resolution.

1. Review Rights. Upon the OIG's delivery to ORHS of its Demand Letter or of its Material Breach Penalty Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, ORHS shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the Stipulated Penalties or Material Breach Penalties sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or Material Breach Penalties shall be subject to review by an ALJ and/or the Departmental Appeals Board (DAB) in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties or Material Breach Penalties shall be made within fifteen (15) days of the date of the Demand Letter or the Material Breach Penalty Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (i) whether ORHS was in full and timely compliance with the obligations of this CIA for which the OIG demands

payment; and, (ii) the period of noncompliance. ORHS shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to whether there was a breach of this CIA and orders ORHS to pay Stipulated Penalties, such Stipulated Penalties shall be due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that ORHS may request review of the ALJ decision by the DAB.

3. Material Breach Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding regarding imposition of the Material Breach Penalty shall be: (a) whether ORHS was in material breach of this CIA; (b) whether ORHS had cured the Material Breach by the date of the Material Breach Penalty Letter; or (c) whether the alleged material breach could not be cured within the thirty-five (35) day period, but that (i) ORHS began to take action to cure the material breach; (ii) ORHS pursued such action with due diligence; and (iii) ORHS provided to the OIG a reasonable timetable for curing the material breach.

If ORHS invokes the Dispute Resolution Procedures in this section, the Material Breach Penalty shall be imposed only after an ALJ decision which is favorable to the OIG. The applicable Material Breach Penalty will be based on the number of days between the date of the Material Breach Penalty Letter and the date of the ALB decision favorable to the OIG. ORHS' election of its contractual right to appeal to the DAB shall

not abrogate the OIG's authority to impose the Material Breach Penalty upon ORHS upon the issuance of the ALJ's decision. If the ALJ sustains the OIG's decision and determines that the imposition of such penalty is authorized, payment of the Material Breach Penalty will be required twenty (20) days after the ALJ issues such a decision notwithstanding that ORHS may request review of the ALJ decision by the DAB.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations.

Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and ORHS agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, ORHS and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns and transferees of ORHS;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

D. The undersigned ORHS signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is

~~signing this CIA in his official capacity and that he is authorized to execute this CIA.~~

ON BEHALF OF ORHS



John Hillenmeyer
President, Orlando Regional Health System, Inc.

1/12/99
DATE

ON BEHALF OF ORHS

Ron Harbert
Counsel for Orlando Regional Health System, Inc.

DATE

J. Stuart Showalter

J. Stuart Showalter
Director of Compliance, ORHS

1/13/1999

DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

4/15/99
DATE